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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|-------------------------|---------------------|------------------|
| 09/585,820 | 06/01/2000 | Thomas J. Mercolono | CDS-221 4698 | |
| 7590 06/30/2004 | | | EXAMINER | |
| Audley A Ciamporcero Jr One Johnson & Johnson Plaza | | | GRUN, JAMES LESLIE | |
| New Brunswick, NJ 08933 | | | ART UNIT | PAPER NUMBER |
| | | | 1641 | |
| | | DATE MAILED: 06/30/2004 | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | |
|--|---|---|--|--|--|
| | 09/585,820 | MERCOLONO ET AL. | | | |
| Office Action Summary | Examiner | Art Unit | | | |
| | James L Grun | 1641 | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply if NO period for reply is specified above, the maximum statutory period who is less than thirty (30) the failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | 36(a). In no event, however, may a reply be within the statutory minimum of thirty (30) d will apply and will expire SIX (6) MONTHS fro cause the application to become ABANDON | timely filed ays will be considered timely. In the mailing date of this communication. NED (35 U.S.C. § 133). | | | |
| Status | • | | | | |
| 1) Responsive to communication(s) filed on 29 As | <u>oril 2004</u> . | | | | |
| , | action is non-final. | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | |
| 4)⊠ Claim(s) <u>16,20,22,23,29,31-37,39-43,45,46,49 and 51</u> is/are pending in the application. | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| 5) Claim(s) 16 and 49 is/are allowed. | | | | | |
| 6)⊠ Claim(s) <u>20,22,23,29,31-37,39-43,45,46 and 51</u> is/are rejected. | | | | | |
| 7) Claim(s) is/are objected to. | | | | | |
| 8) Claim(s) are subject to restriction and/or election requirement. | | | | | |
| Application Papers | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
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| Attachment(s) | 4) Interview Summa | nry (PTO-413) | | | |
| Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail | Date | | | |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) Notice of Informa 6) Other: | Patent Application (PTO-152) | | | |

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 29 April 2004 is acknowledged and has been entered.

Claims 1-15, 17-19, 21, 24-28, 30, 38, 44, 47, 48, and 50 have been cancelled. Claims 16, 20, 22, 23, 29, 31-37, 39-43, 45, 46, 49, and 51 remain in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 20, 22, 23, 29, 31-37, 39-41, and 51 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 20, the relationship of the stained red blood cells to a "group" of those of step (a) are not clear. The examiner would suggest --first-- and --second-- "reagent red blood cells" in

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claim 16; and, in claim 20, --wherein one of said first or second reagent red blood cells are distinguishably stained--.

In claim 29 and claims dependent thereupon, the interrelationships of the components are not clear because the relationship of imaging analysis of the column to imaging analysis of the admixture is not clear. The examiner would suggest, in claim 16, "subjecting the admixture" --in the single column--.

In claims 31-35 and 51, it is not clear what is being determined because the interrelationships of antigens borne on the cell populations to ABO type determined in step d) are not clear.

In claim 33 and claims dependent thereupon, the interrelationships of the components are not clear because the relationship of imaging analysis of the column to imaging analysis of the admixture is not clear. The examiner would suggest, in claim 31, "subjecting the admixture" --in the single column--.

Claims 39-41 depend from a canceled claim.

In claims 36, 37, and 39-41 (assuming dependency of claims 39-41 on claim 36) the interrelationships of the steps and components are not clear, for example because: the relationship of antibody to sample or admixture is not clear; and, the relationship of antibody to first or second antigen or to agglutinate is not clear. Moreover, in claim 39 and claims dependent thereupon, the interrelationships of the components are further not clear because the relationship of imaging analysis of the column to imaging analysis of the admixture is not clear because it is

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not clear that the analysis occurs with the admixture in the single column. The examiner would suggest, in claim 36, "subjecting the admixture" -- in the single column--; or, -- steps (a) through (c) are performed-- in step (d) of claim 36.

Applicant's arguments filed 29 April 2004 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated prior rejections for the reasons repeated above. Claims must clearly and definitely set forth the invention for which applicant desires coverage. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

Claims 42, 43, 45, and 46 are rejected under 35 U.S.C. § 102(b) as being anticipated by Ullman (U.S. Pat. No. 4,584,277) in light of Briggs (U.S. Pat. No. 4,564,598) for reasons similar to those of record.

The teachings of Ullman are as set forth in previous Office actions. In addition, the reference teaches performance of the method in an apparatus (see e.g. cols. 6-7) disclosed in a copending application which matured into the patent of Briggs. In light of Briggs, Ullman intended the reaction means as a single sample holding means specifically taught in Briggs as a "flow tube" (see e.g. col. 7) which meets either the instant tube or column limitation.

Applicant's arguments filed 29 April 2004 have been fully considered but they are not deemed to be persuasive in view of the new grounds of rejection. Applicant urges that newly

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presented limitations of the reaction means serve to distinguish the subject matter of the instant claims from the reagents and apparatus disclosed in the reference. This is not found persuasive for the reasons set forth above.

Claims 16 and 49 are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone numbers for official facsimile transmitted communications to TC 1600, Group 1640, are (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

James L. Grun, Ph.D.

June 28, 2004

CHRISTOPHER L. CHIN **PRIMARY EXAMINER** GROUP 1800/64/

6/28/-4

Christyl L. Chi